

### **REMARKS/ARGUMENTS**

1. Claims 1-13 were previously pending. Claims 3-13 were withdrawn from consideration by the Examiner, as being drawn to a non-elected invention. Claims 1 and 2 were rejected by Office Action dated June 18, 2003. Claims 1 and 2 have been canceled. Claims 14-16 have been added. Upon entry, Claims 14-16 will be under consideration.

It is believed that this amendment places the application in condition for allowance and that therefore entry is appropriate.

2. Added Claims:

Claims 14-16 have been added to this application. New Claims 14 -16 are drawn to the elected invention. Support for these claims can be found in the specification as filed. Specifically, support for the new claims is found at least on Page 8, Lines 25-27, "lack of reciprocity stimulated us to attempt *in vivo* selection of a Florida strain that would have no detectable immunological cross reactivity with the Guelph strain"; Page 14, Lines 24-25, "[B]irds immunized against the Guelph strain no longer recognized the resulting immunovariant *E. maxima* strain, *E. maxima* -I"; Page 15, Lines 9-12, "the derived parasite strain, *E. maxima* -I, behaved similarly in both the Guelph strain-immunized and naïve birds suggesting that all or most immunologically relevant cross reactive epitopes had been selected against and removed from the Florida strain"; Page 16, Lines 1-4, "[T]able 1 shows that *E. maxima* -GPL-immunized birds shed as many oocysts after challenge with the *E. maxima* -I strain as did the non-immunized birds challenged with *E. maxima* -I, indicating no cross-protection. In contrast, the *E. maxima*- GPL- and *E. maxima* -I -immunized birds shed zero or very few oocysts after homologous challenge"; Page 19, Lines 14-18, "[B]ased on the statistical analysis of

these parameters, *E. maxima* -GPL immunization did not protect against *E. maxima*-I challenge, *E. maxima*-I immunization did not protect against *E. maxima*-GPL challenge, and *E. maxima*-ESS immunization did not protect against *E. maxima* -GPL, *E. maxima*-I, or even its homologous challenge with *E. maxima*-ESS"; and Tables 1 and 2.

In accordance with the Examiner's comments, new claims, Claims 14-16, are set forth to claim the variant strain *E. maxima*-I (ATCC number PTA-4959) and other variant strains of *E. maxima* having identifying characteristics corresponding to those of *E. maxima*-I (ATCC number PTA-4959). No new matter has been introduced by amendment.

Applicants hereby request further examination and reconsideration of the application, in view of the amendments and remarks.

3.
  - Claims 1-2 have been rejected under 35 U.S.C. 112, first paragraph.
  - Claims 1-2 have been rejected under 35 U.S.C. 112, second paragraph.
  - Claims 1-2 have been rejected under 35 U.S.C. 102(b).

***Rejections of Claims 1-2 under 35 U.S.C. 112, first paragraph***

4. The Examiner has rejected Claims 1-2 under 35 U.S.C. 112, first paragraph. The Examiner asserts that " it is examiner's position that applicants' statement without an accession number is not sufficient. A viability statement for deposit of biological material must contain the identity of the deposit and the accession number given by the depository. Since the deposit was made after the effective filing date of the application for patent in the United states, a verified statement is required from a person in a

position to corroborate that the *E. maxima*-1 strain described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed." The Examiner further states that when "the original deposit is made after the effective filing date of an application for patent, an applicant is required to promptly submit a statement from a person in a position to corroborate that the biological material which is deposited is a biological material specifically identified in the application ( the filing date of which is relied upon as filed." The Examiner states that "the rejection will not be withdrawn until complete deposit information is disclosed. "

The Examiner had previously stated that "[I]f the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or a statement by an attorney of record over his/her signature and registration number, stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required" (Paper No. 7, Page 6).

5. Applicant has deposited *E. maxima*-1 with the American Type Culture Collection (ATCC), 10801 University Blvd., Manassas, Va. 20110-2209. Applicant is providing, as Exhibit A, a copy of the viability statement for deposit of biological material obtained from the ATCC which contains the identity of the deposit and the accession number given by the depository (See Exhibit A).

Applicant M. Aggie Fernando has stated in her Declaration under 37 CFR 1.132 that

she can corroborate that the *Eimeria maxima*-I strain, disclosed in the instant patent application, was in her laboratory in the Department of Pathobiology, Ontario Veterinary College, University of Guelph, Guelph, Ontario, Canada N1G2W1, prior to the filing date for the application of April 20, 2001 until said *Eimeria maxima*-I strain was sent to the American Type Culture Collection (ATCC), 10801 University Blvd., Manassas, Va. 20110-2209 where it was deposited on July 25, 2002 (Paragraph 3 of the Declaration of M. Aggie Fernando); that she can confirm that during the time that the *E. maxima*-I strain was in her laboratory, the clonal population was stored as oocysts in the refrigerator or as sporocysts in DMSO in liquid nitrogen and that the clonal population was being expanded in chickens in a pathogen-free environment of a Level III isolation facility in order to obtain the numbers of live oocysts required for deposit by the ATCC (Paragraph 4 of the Declaration of M. Aggie Fernando); and that she can further state that the amount of time that was involved to obtain the numbers of live oocysts required by the ATCC and to obtain the necessary documentation to ship the live oocysts across the U.S./Canadian border was the reason that necessitated depositing the oocysts in July, 2002, after the filing date of April 20, 2001 (Paragraph 5 of the Declaration of M. Aggie Fernando). She further states that the *Eimeria maxima*-I strain disclosed in the above identified U.S. patent application filed April 20, 2001 is the same as that deposited with the ATCC on July 25, 2002 as ATCC number PTA-4959 (Paragraph 6 of the Declaration of M. Aggie Fernando).

The specification has been amended to disclose that *E. maxima*-I was deposited on July 25, 2002 as ATCC accession number PTA-4959 (Page 11, Lines 24-28). The specification discloses that the deposit was made under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure and that "all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the

depository is required" (Page 12, Lines 15-18). However, in addition, Applicant Harry Danforth has stated in his Declaration under 37 CFR 1.132 that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty (Paragraph 2 of the Declaration of Harry Danforth), that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application (Paragraph 3 of the Declaration of Harry Danforth) and that the deposit will be replaced if viable samples cannot be dispensed by the depository (Paragraph 4 of the Declaration of Harry Danforth). He further states that the *Eimeria maxima*-I strain disclosed in the above identified U.S. patent application filed April 20, 2001 is the same as that deposited with the ATCC on July 25, 2002 as ATCC number PTA-4959 (Paragraph 5 of the Declaration of Harry Danforth).

Claims 1 and 2 have been canceled. In response to the Examiner's remarks, the claims have been rewritten so that they recite the correct ATCC accession number, PTA-4959, of the deposited *E. maxima*-1.

In view of the amendment and above remarks, it is respectfully requested that the rejection under 35 U.S.C. paragraph 112, first paragraph, be withdrawn.

***Rejections of Claims 1-2 under 35 U.S.C. 112, second paragraph***

6. The Examiner has rejected Claims 1-2 under 35 U.S.C. 112, second paragraph, as "being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." The Examiner asserts that the term "immunovariant" in claims 1-2 is a relative term which renders the claim indefinite. The Examiner further asserts that "neither the claims nor the specification define immunovariant. It is unclear how little or how much variation is required for a strain to

be considered an immunovariant" (Page 7).

In response to the Examiner's remarks, Applicant has amended the claims to refer to the *Eimeria maxima*-I strain as a variant of the strain *Eimeria maxima* and to list identifying characteristics of *Eimeria maxima*-I, deposited as ATTC number PTA-4959. The characteristics, as exemplified in the specification, describe immunological properties which identify *Eimeria maxima*-I.

In view of the amendment and above remarks, it is respectfully requested that the rejection of Claims 1 and 2 under 35 U.S.C. paragraph 112, second paragraph, be withdrawn.

7. The Examiner has rejected Claim 2 under 35 U.S.C. 112, second paragraph, as "being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." The Examiner asserts that "the phrase 'corresponds in characteristics to the strain *E. maxima*-I' in claim 2 is a relative term which renders the claim indefinite. There is no definition of what characteristics are required of strain in order for it to correspond to said strain" (Page 7).

In response to the Examiner's remarks, Applicant has amended the claims to refer to the *Eimeria maxima*-I strain as a variant of the strain *Eimeria maxima* and to list identifying characteristics of *Eimeria maxima*-I, deposited as ATTC number PTA-4959. The characteristics, as exemplified in the specification, describe immunological properties which identify *Eimeria maxima*-I and define what characteristics are required of a strain in order for it to correspond to *Eimeria maxima*-I.

In view of the amendment and above remarks, it is respectfully requested that the rejection of Claims 1 and 2 under 35 U.S.C. paragraph 112, second paragraph, be withdrawn.

***Rejection of Claims 1-2 under 35 U.S.C.102 (b) Over Barta et al.***

8. The Examiner has rejected Claims 1-2 under 35 U.S.C. 102 (b) as being anticipated by Barta *et al.* (International J. for Parasitology, Vol. 28, pp. 485-492, 1998).

The Examiner states that "the claims do not recite an ATCC accession number; applicants' claims are not limited as argued. Applicants' claims are interpreted as being significantly broader, and thereby incorporate any antigenic variation of *E. maxima*" (Paper No. 9, Page 8, Lines 6-8). The Examiner further states "it is noted that the features upon which applicant relies *i.e.*, protection against challenges with *E. maxima*-I are not recited in the rejected claims" and that since "applicants have failed to claim the deposited strain, the strains of Barta *et al.*, meet the broad requirements of the claim. It is noted that the claims fail to recite which characteristics of *E. maxima*-I must correspond" (Paper No. 9, Page 8, Lines 12-13 and Lines 17-20, respectively).

Claims 1 and 2 have been canceled. Claims 14-16 replace Claims 1 and 2. This rejection is overcome since it is believed that new Claims 14-16 patentably distinguish from Barta *et al.*

In response to the Examiner's remarks, new Claims 14-16 replace Claims 1-2 and recite the ATCC accession number, PTA-4959, of the deposited *E. maxima*-I. In addition, in response to the Examiner's remarks, new Claims 15-16 recite characteristics of *E. maxima*-I (ATCC number PTA-4959), *i.e.*, that immunization with *E. maxima*-I (ATCC number PTA-4959) protects against challenge with *E. maxima*-I (ATCC number PTA-4959) but does not protect against challenge with the Guelph strain of *E. maxima*, designated *E. maxima*-GLP, an indication that *E. maxima*-I (ATCC number PTA-4959) has no detectable immunological cross reactivity with *E. maxima*-

GLP.

Barta *et al.* do not disclose the ATCC accession number, PTA-4959, of the deposited *E. maxima*-I nor do they disclose that immunization with *E. maxima*-I (ATCC number PTA-4959) does not protect against challenge with the Guelph strain of *E. maxima*, designated *E. maxima*-GLP, an indication that *E. maxima*-I (ATCC number PTA-4959) has no detectable immunological cross reactivity with *E. maxima*-GLP, recited in the instant claims and disclosed in the instant specification. Barta *et al.* do not disclose strains having the same characteristics as *E. maxima*-I. Since the strains of Barta *et al.* do not share the corresponding characteristics of those recited in the claims, Barta *et al.* do not anticipate the claimed invention.

In view of the above added and canceled claims and remarks, it is respectfully requested that the rejection of Claims 1 and 2 under 35 U.S.C. 102(b) be withdrawn.

***Rejection of Claims 1-2 under 35 U.S.C.102 (b) Over Martin et al.***

9. The Examiner has rejected Claims 1-2 under 35 U.S.C. 102(b) as being anticipated by Martin *et al.* (International J. for Parasitology, Vol. 27 (5), pp. 527-533, 1997).

The Examiner states that "Martin *et al.* teach an immunovariant strain of *Eimeria maxima*, and an immunovariant strain of *Eimeria maxima* that corresponds in characteristics to the strain *E. maxima*-I as claimed" (Paper No. 9, Page 9, Lines 7-9). The Examiner further states that "the claims do not recite an ATCC accession number; and applicants' claims are not limited as argued. Applicants' claims are interpreted as being significantly broader based on the broad claim language and lack of claiming a deposited strain or a strain with any functional or structural characteristics (Paper No. 9,



Page 9, Lines 11-14). The Examiner states that "it is noted that the features upon which applicant relies, *i.e.*, protection against challenges with *E. maxima*-I are not recited in the rejected claims (Paper No. 9, Page 9, Lines 16-18).

Claims 1 and 2 have been canceled. Claims 14-16 replace Claims 1 and 2. This rejection is overcome since it is believed that new Claims 14-16 patentably distinguish from Barta *et al.*

In response to the Examiner's remarks, new Claims 14-16 replace Claims 1-2 and recite the ATCC accession number, PTA-4959, of the deposited *E. maxima*-I. In addition, in response to the Examiner's remarks, new Claims 15-16 recite characteristics of *E. maxima*-I (ATCC number PTA-4959), *i.e.*, that immunization with *E. maxima*-I (ATCC number PTA-4959) protects against challenge with *E. maxima*-I (ATCC number PTA-4959) but does not protect against challenge with the Guelph strain of *E. maxima*, designated *E. maxima*-GLP, an indication that *E. maxima*-I (ATCC number PTA-4959) has no detectable immunological cross reactivity with *E. maxima*-GLP.

Martin *et al.* do not disclose the ATCC accession number, PTA-4959, of the deposited *E. maxima*-I nor do they disclose that immunization with *E. maxima*-I (ATCC number PTA-4959) does not protect against challenge with the Guelph strain of *E. maxima*, designated *E. maxima*-GLP, an indication that *E. maxima*-I (ATCC number PTA-4959) has no detectable immunological cross reactivity with *E. maxima*-GLP, disclosed in Martin *et al.* Since the strains of Martin *et al.* do not share the corresponding characteristics of those recited in the claims, Martin *et al.* do not anticipate the claimed invention.

In view of the above added and canceled claims and remarks, it is respectfully requested that the rejection of Claims 1 and 2 under 35 U.S.C. 102(b) be withdrawn.

### CONCLUSION

In view of the above amendments and remarks, it is believed that all of the claims and the specification are in condition for allowance. Accordingly, it is respectfully requested that the rejections be withdrawn and that the instant application be allowed to issue. If any issues remain to be resolved, the Examiner is invited to telephone the undersigned at the number below.

Respectfully submitted,

December 18, 2003

Date

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\* Evelyn M. Rabin \*

\* (Name of applicant, assignee, or Registered Representative) \*

\* Evelyn M. Rabin December 18, 2003 \*  
\* (Signature) (Date) \*

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